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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/047,068 04/16/93 WEINBERG

EXAMINER
J 20039800646

ART UNIT	PAPER NUMBER
DAVENPORT, A	22

18M2/0420

NIXON AND VANDERHYE, P.C.  
1100 NORTH GLEBE RD., 8TH FL.  
ARLINGTON, VA. 22201-4714

DATE MAILED:  
1811

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

04/20/94

☐ This application has been examined ☒ Responsive to communication filed on 3/3/94 ☒ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), \_\_\_\_\_ days from the date of this letter.  
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- |   |   |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892.        | 2. <input type="checkbox"/> Notice of Draftsman's Patent Drawing Review, PTO-948. |
| 3. <input checked="" type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449.  | 4. <input type="checkbox"/> Notice of Informal Patent Application, PTO-152.       |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____   |

Part II SUMMARY OF ACTION

1. ☒ Claims 8-15 are pending in the application.  
Of the above, claims \_\_\_\_\_ are withdrawn from consideration.
2. ☒ Claims 1-7 have been cancelled.
3. ☐ Claims \_\_\_\_\_ are allowed.
4. ☒ Claims 8-15 are rejected.
5. ☐ Claims \_\_\_\_\_ are objected to.
6. ☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on \_\_\_\_\_. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on \_\_\_\_\_, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed \_\_\_\_\_, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. \_\_\_\_\_; filed on \_\_\_\_\_.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

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Claims 8-15 are pending in the instant application. Claims 1-7 have been canceled and new claims 8-15 have been added as requested by applicant's in their communication filed December 23, 1993. The Declaration and references are also acknowledged from the communication filed March 3, 1994.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of claims 1-3 and 6 under 35 U.S.C. 112, first paragraph is withdrawn in view of the amendment filed December 23, 1993 canceling said claims.

The rejection of claims 1, 3 and 6 under 35 U.S.C. § 103 as unpatentable over Haynes et al. (1989) in view of St. John et al. is withdrawn in view of the cancellation of said claims in the amendment filed December 23, 1993.

The rejection of claims 8-15 under 35 USC § 101, i.e. lack of utility, is maintained. The rejection is maintained for essentially the same reasons as the rejection under this statute and subsection as applied to claims 4,5 and 6 as set forth in the previous office action. Applicants arguments filed December 23, 1993 and March 3, 1994 were fully considered but were not deemed persuasive. Applicants present the Declaration and the Rivadeneira et al. publication in support of the assertion that "the in vitro data provided in the application can be expected to be predictive of efficacy in vivo" (see page 4 of Dec. 23, 1993

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amendment). The reference states "These results suggest that CD44 may be a determinant of HIV-1 infection of mononuclear phagocytes in vitro" see abstract. The reference also states "This work may help in the development of novel strategies for preventing or controlling HIV-1 infection; anti-CD44 could prove useful therapeutically" see page 9. In both instances cited the reference uses languages that is indefinite such as may and suggests, etc... This terminology leads one to conclude that the work done is speculative and the tests per se are therefore speculative. There is no clear cut evidence that the assay and other test data in the instant specification would be predictive of In vivo applicability. Applicant's also state "... the Examiner is remained that the recited agents can be used to lessen infectability of HIV in <sup>products designed for infusion</sup> (e.g. blood derived transfusion products)". The ultimate use of the instant invention is to inhibit HIV infection in a patient. The blood products must ultimately be returned to or used by a patient.

Utility must be definite and in currently available form; (Brenner v. Manson, 383 U.S. 519, 148 USPQ 689) not merely for further investigation or research but commercial availability is not necessary. Proof of utility under this section may be established by clinical or in vivo or in vitro data, or combinations of these which would be convincing to those skilled in the art. (In re Irons, 52 CCPA 938, 340 F.2d 924, 144 USPQ

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351. More particularly, if the utility relied on is directed solely to the treatment of humans, evidence of utility, if required, must generally be clinical evidence, (Ex parte Timmis, 123 USPQ 581) although animal tests may be adequate where the art would accept these as appropriately correlated with human utility. In re Hartop et al., 50 CCPA 780, 311 F. 2d 249, 135 USPQ 419; Ex parte Murphy, 134 USPQ 134.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Avis Davenport whose telephone number is (703) 308-4002.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

*Am*  
Davenport/em  
March 22, 1994

*Lee L. Lee*  
LESTER L. LEE  
PRIMARY PATENT EXAMINER  
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